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| APPLICATION NO.                                | PPLICATION NO. FILING DATE |              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|--|----------------------------|--------------|----------------------|-------------------------|------------------|--|
| 09/643,277                                     |                            | 08/22/2000   | M. Bud Nelson        | B-28                    | B-28 8660        |  |
| 21130  | 7590                       | 07/18/2003   |                      | •                       |                  |  |
|  | •                          | LANDER, COPL | EXAMINER             |                         |                  |  |
| ATTN: IP DEPARTMENT DOCKET CLERK 2300 BP TOWER |                            |              |                      | SAUNDERS, DAVID A       |                  |  |
| 200 PUBLI<br>CLEVELA                           |                            |              |                      | ART UNIT PAPER NUMBER   |                  |  |
|  | •                          |              |                      | 1644                    | 1/2-             |  |
|  |                            |              |                      | DATE MAILED: 07/18/2003 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)  |  |
|--|---|---|--|
| Advisory Action  | 09/643,277  | NELSON ET AL.   |  |
| Advisory Addion  | Examiner  | Art Unit  |  |
|  | David A Saunders, PhD   | 1644  |  |
| The MAILING DATE of this communication appe  | ars on the cover sheet with the c   | correspondence addi   | ress   |
| THE REPLY FILED 5/15/03 FAILS TO PLACE THIS AF Therefore, further action by the applicant is required to a final rejection under 37 CFR 1.113 may only be either: (condition for allowance; (2) a timely filed Notice of Appetexamination (RCE) in compliance with 37 CFR 1.114.   | void abandonment of this application (1) a timely filed amendment whi   | cation. A proper rep<br>ch places the applic  | cation in  |
| PERIOD FOR RE  | PLY [check either a) or b)]   |   |  |
| a) The period for reply expires <u>3</u> months from the mailing date of   |   |   |  |
| b) The period for reply expires on: (1) the mailing date of this Advevent, however, will the statutory period for reply expire later the ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f).  Extensions of time may be obtained under 37 CFR 1.136(a). The danave been filed is the date for purposes of determining the period of extensions of the shortened (b) above, if checked. Any reply received by the Office later than three most partner adjustment. See 37 CFR 1.704(b).   | an SIX MONTHS from the mailing date of<br>FILED WITHIN TWO MONTHS OF THI<br>te on which the petition under 37 CFR 1.1<br>sion and the corresponding amount of the<br>I statutory period for reply originally set in | f the final rejection. E FINAL REJECTION. S I 36(a) and the appropriate fee. The appropriate extended the final Office action; or a | e extension fee<br>ension fee under<br>(2) as set forth in |
| 1. A Notice of Appeal was filed on Appellant's 37 CFR 1.192(a), or any extension thereof (37 CF  |   |   |  |
| 2. The proposed amendment(s) will not be entered b   | ecause:   |   |  |
| (a)  they raise new issues that would require furth  | er consideration and/or search (  | see NOTE below);  |  |
| (b) they raise the issue of new matter (see Note because of the second o | pelow);   |   |  |
| (c) they are not deemed to place the application issues for appeal; and/or   | in better form for appeal by mat  | erially reducing or s   | implifying the   |
| (d) they present additional claims without cancel NOTE:  | ing a corresponding number of   | finally rejected clain  | ns.  |
| 3. Applicant's reply has overcome the following rejection  | ction(s):   |   |  |
| 4 Newly proposed or amended claim(s) would canceling the non-allowable claim(s).   | be allowable if submitted in a s  | eparate, timely filed   | d amendment  |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request fo application in condition for allowance because: Se   |   | sidered but does NC   | T place the  |
| 6. The affidavit or exhibit will NOT be considered be raised by the Examiner in the final rejection.   | cause it is not directed SOLELY   | to issues which we  | re newly   |
| 7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims were appeared to the control of the control    |   |   | and an   |
| The status of the claim(s) is (or will be) as follows:   |   |   | '  |
| Claim(s) allowed:  |   |   |  |
| Claim(s) objected to:  | •   |   | •  |
| Claim(s) rejected: 11-17,20-28,31-40 and 46-62.  |   |   |  |
| Claim(s) withdrawn from consideration:   |   |   |  |
| 8. The proposed drawing correction filed on is   | a) ☐ approved or b) ☐ disapp  | proved by the Exam  | iner.  |
| 9. Note the attached Information Disclosure Stateme  | nt(s)( PTO-1449) Paper No(s).   | <u></u> •   |  |
| 10. Other:   |   |   |  |
| •  |   |   |  |
|  |   |   |  |
|  |   |   |  |

Continuation Sheet (PTO-303) 09/643,277

Continuation of 5, does NOT place the application in condition for allowance because: Applicant's response has clarified the record as to what he intends to claim by reciting "indicator". For what applicant intends, the term --indication-- would be more appropriate than "indicator" in claims 10, 20, 32 and 54. The term "indication" is conventionally used in claim language for clinical diagnostic methods, in a concluding step that relates the presence/amount of a diagnostic marker to the presence/absence/stage/course of a disease condition. The term "indicator", on the other hand, implies a chemical entity which provides a signal response in an assay. The fact that applicant used the term "indicator" as an entity to be claimed (nonelected claims 18-19, 29-30, 41-42) implied to the examiner that the term "indicator meant some physical/chemical entity and led to confusion in examination of elected claims.

Claims 10, 20, 31, 46 and 54 remain confusing by failing to recite how the affinity ligand which does not comprise a detection reagent participates to form any sort of complex, to which the affinity ligand which comprises a detection reagent becomes bound (Nothing ev n recites that a complex including these two affinity ligands is formed). While applicant's urgings may be enlightening, the claims per se must clearly define the cooperative relationship of all of the recited reagents, without which there is a gap in the claimed method steps.

Regarding the terms "comparing" and "difference", the examiner concurs that these need not be interpreted in any mathematical sense.

David a Launders

PRIMARY EXAMINER

ART UNIT 182/6500